MAR 2 7 2002

K020611

Universal Bone Plate III System
510(k) SUMMARY

Submitted by:	Spinal Concepts, Inc. 12012 Technology Blvd. Suite 100 Austin, TX 78727
Contact Person:	David M. Hooper, Ph.D. Manager, Clinical & Regulatory Affairs
Establishment Registration Number:	1649384
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories. (87HRS)
Device Classification:	Class II
Common Name:	Titanium Bone Plate and Screws
Date prepared:	February 22, 2002
Predicate Device	SCI Universal Bone Plate II System (K973586). This is a design modification per established design control procedures.

DEVICE DESCRIPTION

The UBP III System consists of single and multi-segmented titanium bone plates of various sizes and lengths, titanium bone screws in 3.5 and 4.0mm diameters and various lengths, and associated instrumentation. Fixation is provided by the insertion of bone screws through the openings in the plate.

INTENDED USES/INDICATIONS

The UBP System III is intended to bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist, and hand.

MECHANICAL TEST DATA

Mechanical testing data were collected to verify the design changes. Static and fatigue data were provided to demonstrate that the design changes met design requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

David M. Hooper, Ph.D.
Manager, Clinical and Regulatory Affairs
Spinal Concepts, Inc.
12012 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K020611
Trade/Device Name: Universal Bone Plate III System (UBP III)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: February 22, 2002
Received: February 26, 2002

Dear Dr. Hooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020611

Device Name: Spinal Concepts, Inc. **Universal Bone Plate III System**

Indications for Use: The UBP System III is intended to bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist, and hand.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(Per 21 CFR 801.109)

OR

Over-The-Counter
(Optional Format 1/2/96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020611